SYNTHES® Spine

MAR - 9 2010

510(k) Summary

Name of Firm:	Synthes Spine 1302 Wrights Lane East West Chester, PA 19380
510(k) Contact:	Heather Guerin Regulatory Affairs Specialist Telephone: 610-719-5432 Facsimile: 610-719-5102 Email: guerin.heather@synthes.com
Date Prepared:	February 8, 2010
Trade Name:	Synthes Matrix MIS Rods
Classification:	21 CFR 888.3070 –Pedicle screw spinal system Class III Orthopaedic and Rehabilitation Devices Panel Product Code: NKB, MNH, MNI, KWQ, KWP
Predicates:	The Synthes Matrix MIS Rods are substantially equivalent to similar, previously cleared pedicle screw spinal systems.
Device Description:	The Synthes Matrix MIS Rods are spinal rods to be used as part of the Synthes Matrix System of posterior pedicle screw fixation implants. The titanium rods are available straight or curved in two bend radii and a range of lengths. The Synthes Matrix MIS rods are to be implanted via a minimally invasive approach. The Synthes Matrix MIS Rods are intended to be used with the Synthes Matrix System Implants. The Synthes Matrix Implants consist of a family of non-cervical spinal fixation devices intended for use as a posterior pedicle screw fixation system (T1-S2), posterior hook fixation system (T1-L5) or anterolateral fixation system (T8-L5).
Intended Use/ Indications for Use:	The Synthes USS (including Matrix, USS Side-Opening, USS Dual-Opening, USS Small Stature (which includes small stature and pediatric patients), USS VAS variable axis components, USS Fracture, Click'X, Click'X Monoaxial, Pangea, Pangea Monoaxial, USS Polyaxial, USS Iliosacral, and ClampFix) are non-cervical spinal fixation devices intended for use as posterior pedicle screw fixation systems (T1-S2/ilium), a posterior hook fixation system (T1-L5), or as an anterolateral fixation system (T8-L5). Pedicle screw fixation is limited to skeletally mature patients with the exception of the Small Stature USS. These devices are indicated as an adjunct to fusion for all of the following indications regardless of the intended use: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, and failed previous fusion (pseudoarthrosis). When treating patients with Degenerative Disc Disease (DDD), transverse bars are not cleared for use as part of the posterior pedicle screw construct. When used with the 3.5/6.0-mm parallel connectors, the Synthes USS (including USS Side-Opening, USS Dual-Opening, USS VAS variable axis components, USS Fracture, Click'X, Click'X Monoaxial, Pangea, Pangea Monoaxial, USS Polyaxial, USS Iliosacral, and ClampFix) can be linked to the CerviFix 3.5 mm Systems (including CerviFix, Axon, and Synapse). In addition, when used with 3.5/5.0 mm parallel connectors, the Synthes Small Stature USS can be linked to the CerviFix

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	3.5 mm Systems (including CerviFix, Axon, and Synapse). When used with the 5.0/6.0mm parallel connectors, the Synthes Small Stature USS can be linked to the Synthes USS (including USS Side-Opening, USS Dual-Opening, USS VAS variable axis components, USS Fracture, Click'X, Click'X Monoaxial, Pangea, Pangea Monoaxial, USS Polyaxial, USS Iliosacral, and ClampFix). In addition, Synthes USS (including USS Side-Opening, USS Dual-Opening, USS VAS variable axis components, USS Fracture, Click'X, Click'X Monoaxial, Pangea, Pangea Monoaxial, USS Polyaxial, USS Iliosacral, and ClampFix) can be interchanged with all USS 6.0 mm rods and transconnectors.
Comparison of the device to predicate device(s):	The Synthes Matrix MIS Rods are a result of modifications to the design and surgical technique of the predicate devices. They are substantially equivalent to the predicates in design, function, material and intended use.
Performance Date (Non-Clinical and/or Clinical):	*Non-Clinical Performance and Conclusions:* The information provided demonstrates that the Synthes Matrix MIS Rods are substantially equivalent to the predicate devices. *Clinical Performance and Conclusions:* Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Synthes Spine
% Ms. Heather Guerin
Regulatory Affairs Specialist
1302 Wrights Lane East
Chester, Pennsylvania 19380

MAR - 9 2010

Re: K093668
Trade/Device Name: Synthes Matrix MIS Rods
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI, KWQ, KWP
Dated: February 08, 2010
Received: February 17, 2010

Dear Ms. Guerin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Buchman for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number: K093668
Device Name: Synthes Matrix MIS Rods

Indications for Use:

The Synthes USS (including Matrix, USS Side-Opening, USS Dual-Opening, USS Small Stature (which includes small stature and pediatric patients), USS VAS variable axis components, USS Fracture, Click'X, Click'X Monoaxial, Pangea, Pangea Monoaxial, USS Polyaxial, USS Iliosacral, and ClampFix) are non-cervical spinal fixation devices intended for use as posterior pedicle screw fixation systems (T1-S2/ilium), a posterior hook fixation system (T1-L5), or as an anterolateral fixation system (T8-L5). Pedicle screw fixation is limited to skeletally mature patients with the exception of the Small Stature USS. These devices are indicated as an adjunct to fusion for all of the following indications regardless of the intended use: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, and failed previous fusion (pseudoarthrosis).

When treating patients with Degenerative Disc Disease (DDD), transverse bars are not cleared for use as part of the posterior pedicle screw construct.

When used with the 3.5/6.0-mm parallel connectors, the Synthes USS (including USS Side-Opening, USS Dual-Opening, USS VAS variable axis components, USS Fracture, Click'X, Click'X Monoaxial, Pangea, Pangea Monoaxial, USS Polyaxial, USS Iliosacral, and ClampFix) can be linked to the CerviFix 3.5 mm Systems (including CerviFix, Axon, and Synapse). In addition, when used with 3.5/5.0 mm parallel connectors, the Synthes Small Stature USS can be linked to the CerviFix 3.5 mm Systems (including CerviFix, Axon, and Synapse). When used with the 5.0/6.0mm parallel connectors, the Synthes Small Stature USS can be linked to the Synthes USS (including USS Side-Opening, USS Dual-Opening, USS VAS variable axis components, USS Fracture, Click'X, Click'X Monoaxial, Pangea, Pangea Monoaxial, USS Polyaxial, USS Iliosacral, and ClampFix).

In addition, Synthes USS (including USS Side-Opening, USS Dual-Opening, USS VAS variable axis components, USS Fracture, Click'X, Click'X Monoaxial, Pangea, Pangea Monoaxial, USS Polyaxial, USS Iliosacral, and ClampFix) can be interchanged with all USS 6.0 mm rods and transconnectors.

Prescription Use X (21 CFR 801 Subpart D)	AND / OR	Over-the-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093668